IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Smith

Serial No.: 10/670,378

Examiner: Claytor, D. R.

Art Unit 1617

Filing Date: September 26, 2003

For: Method of Making a Lanolin Free Absorption Base (as amended)

PRE-APPEAL REQUEST

Commissioner of Patents
Alexandria, VA 22313-1450

Sir:

In connection with the Notice of Appeal filed concurrently herewith, Appellants wishes to have a review of the factual and legal bases for the final rejection of the claims based on United States Patent No. 4,788,001 to Narula in view of United States Patent No. 6,153,208 to McAtee.

The facts and reasoning related to the rejection can be gleaned from Applicant's filing of March 7, 2008. It is asserted that the Examiner has committed clear legal error in alleging that the claims are obvious under 35 U.S.C. § 103(a) based on Narula as modified by McAtee.

NARULA AND MCATEE ARE NOT SIMILAR IN PURPOSE SUCH THAT THEIR RESPECTIVE COMPOSITIONS CAN BE COMBINED IN ANY FASHION

A first primary reason that the rejection is improper is the contention that the compositions of Narula and McAtee are so similar that they can be readily combined to arrive at the invention.

It is fair to say that the emulsions of Narula include the combination of petrolatum and water. What is not fair to say is that McAtee is so similar to Narula such that the Examiner can pluck selected teachings of McAtee and combine them with Narula to allege that the inventive method is *prima facie* case of obvious.

McAtee and Narula are fundamentally different in that McAtee excludes moisture in his formulation, whereas Narula requires water in a specific amount.

In the rejection, the Examiner states that McAtee teaches methods of making compositions with a conditioning emulsion comprised of an oil soluble conditioning agent, including petrolatum, see col. 25, line 58 and col. 26, lines 13-21, and methyl glucose dioleate as the emulsifier, see col. 30, line 53. Essentially, the invention of McAtee is comprised of a water-insoluble substrate (such as a multi-layered pad), a lathering product to produce a foaming effect, and a variety of optional elements such as a conditioning emulsion. Critical to note here is that McAtee goes to great lengths to stress the necessity for the exclusion of moisture in the invention. For instance, it is stated, "The

term 'water- activated,' as used herein, means that the present invention is presented to the consumer in dry form to be used after it is wetted with water. It is found that these articles produce a lather or are 'activated' by contacting them with water and then further subjecting the article to mechanical forces, such as rubbing.", see Col. 7, lines 57-62.

Additionally, it is stated that, " The term "substantially dry," as used herein, means that prior to use the article is substantially free of water and generally feels dry to the touch...(and will preferably contain) less than 1% by weight of water...", see col. 7, lines 63-67 and col. 8, lines 1-2.

As importantly, the discussion by McAtee as to the makeup of the conditioning agent is insightful in assessing whether the Narula and McAtee are properly combined to support the contention that the invention is obvious. McAtee states "The term "conditioning emulsion" as used herein means the combination of an internal phase comprising a water soluble conditioning agent that is enveloped by an external phase comprising an oil soluble agent.", see col. 28, lines 66-67 and col. 29, lines 1-2. Thus, McAtee makes very clear that only a water-in oil (w/o) composition will suffice for the invention and makes no statements as to the making of or utility of an oil-in-water (o/w) product, the internal phase being oil soluble components.

Comparing Narula and McAtee reveals that the two are not useful for the same purpose. McAtee is concerned with formulating a water-free composition that is to be later combined with water during the use thereof. In contrast, Narula is concerned with preparing an oil-in-water emulsion that uses a nonionic surfactant for improved stability. While it is true that both use the term "emulsion", this fact alone does not give the Examiner free rein to ignore the true intent of the references so as to formulate a rejection based on 35 U.S.C. § 103(a).

Applicant submits that it is error to merely conclude that the compositions of McAtee can be combined to produce the invention when the McAtee and Narula are not similar in their aims or the means by which the aims are reached. Therefore, it is not proper to say that because the claim terms found in claims 6 and 17 can be found amongst the words of Narula and McAtee that the claims are obvious under 35 U.S.C. § 103(a). The Examiner must always have a reason for making a rejection alleging obviousness that is supported with an objective factual basis. In this case, the proper foundation to support the contention of obviousness is lacking and this fatally taints the rejection such that it could not be sustained on appeal.

THE ASSERTION THAT THE MIXING TEMPERATURES ARE OBVIOUS BASED ON MCATEE IS IMPROPER

Applicant also takes issue with the reliance on the mixing temperatures of McAtee as grounds to contend that the heating step of claims 6 and 17 is obvious. In review, claims 6 and 17 require heating of the petrolatum prior to adding of the MGD. In the rejection, the Examiner states

that the conditioning emulsion ingredients of McAtee can be heated to 75-115 °C, citing Examples 6-10, so that the step of heating of the petrolatum to up to 80 °C prior to addition of the MGD is obvious.

It is submitted that the Examiner is confusing the need for increasing the lipid hardness of McAtee with the mere combination of water and petrolatum of Narula. For "lipid hardness", McAtee states "The lipid hardness value is a physical hardness measurement of the combination of all the conditioning agents within the conditioning component", see col. 31, lines 2-28. These materials require high melting temperatures, up to 250 °C, see col. 32, lines 8-12. In fact, it is not just examples 6-10 that have high mixing temperatures; such temperatures are used in all ten examples.

Given that McAtee uses high mixing temperatures because high melting point lipid hardness-increasing components are used in the conditioning component, the question becomes whether this leads to the step of heating petrolatum up to 80 °C prior to the addition of MGD.

It is submitted that the fact that McAtee uses these high mixing temperatures in his method does not mean that one of skill in the art would use such temperatures when making the composition of Narula. Narula is merely combining an oil phase, nonionic surfactants, and an aqueous phase and expresses no need for a heating step in this part of the method. McAtee does not provide the reason to modify Narula with the claimed heating step since the essential high melting point constituents used in McAtee for lipid hardness are not present in Narula nor is there any reason to include their presence absent the use of hindsight.

In fact, the invention runs counter to McAtee. As explained on page 3 of the specification, one goal of the invention is to eliminate the requirement of high melting point materials. One feature of the invention is that the components of the inventive absorption base or occlusive base can sustain high temperatures for the inclusion of high melting active ingredients without damage to the emulsion. In contrast, McAtee's conditioning emulsions must have high temperatures to be made. In fact, it is exactly these "lipid hardeners" and their high melting temperatures that are not a required component in the invention. Despite their absence in the base, the invention still facilitates the smooth application of products over a range of temperatures on human skin.

THE ALLEGATION THAT McATEE SUPPORTS THE CONTENTION THAT THE WATER CAN BE PREHEATED IS IMPROPER

In the rejection, the Examiner concludes that "it would be obvious to vary and/or optimize the temperature to dilute the emulsion with water at 50 °C provided in the composition, according to the guidance of McAtee." This assertion is improper for a number of reasons. First, the issue is whether it would be obvious to dilute a mixture of petrolatum that was heated up to 80 °C and MGD using preheated water. McAtee, as noted above, does not use any water in the conditioning component. Thus, it is not understood how McAtee's teachings provide the asserted motivation.

Secondly, the temperature of mixing of McAtee relates to the presence of high melting point constituents for lipid hardness. However, the issue here is preheating of the water used to dilute the mixture. It is not seen how the requirement of mixing the high melting point constituents at an elevated temperature translates to the conclusion that one would preheat the water used to dilute the claimed mixture. The reasoning for this aspect of the rejection is improper and this is another reason why a *prima facie* case of obviousness is not established based on Narula and McAtee.

ALLEGING THAT IT IS OBVIOUS TO OBTAIN THE AIM OF THE INVENTION IS NOT A PROPER REASON TO BASE A REJECTION UNDER 103

In the rejection, the Examiner concludes with the statement that "it would be obvious to a person of ordinary skill in the art to make an absorption base with excellent emulsifying properties." This reasoning cannot support a rejection based on 35 U.S.C. § 103(a) since it lacks any objective basis in fact. While many inventors strive to make an absorption base with better properties, making this observation is unrelated to the issue of obviousness at hand. The real question is whether the method of each of claims 6 and 17 is obvious based on the teachings of the prior art and knowledge of the artisan. The answer to this question is that the inventive method is not obvious because it cannot be gleaned from the teachings of Narula and McAtee, particularly since the two references are at odds with each other and can not be properly combined.

THE ARGUMENT CITING MOTIVATION IS FLAWED

In the rejection, the Examiner also makes the observation "that it would be obvious to make an absorption base comprised of petrolatum and methyl glucose dioleate because of the teachings of Narula and McAtee et al. that both agent (sic) are used as emulsifiers... ". This reasoning is improper since it fails to consider the claims at issue. The issue is not the mere combination of MGD and petrolatum, but the method of making an absorption base according to claims 6 and 17. Therefore, the fact the petrolatum and MGD are known does not mean that the method described in each of claims 6 and 17 is obvious. These claims are not composition claims nor does the method merely recite the steps of mixing petrolatum and MGD together. Consequently, the observation that Narula and McAtee teach the petrolatum and MGD "are both agent (sic) used as emulsifiers" cannot be the basis for a rejection under 35 U.S.C. § 103(a).

In addition, the statement "are both agent (sic) used as emulsifiers" appears to be technically incorrect if "both agent" refers to petrolatum and MGD as emulsifiers. MGD is an emulsifier that, when combined with petrolatum, produces an emulsified mixture, i.e., the claimed absorption base. Therefore, the rejection under 35 U.S.C. § 103(a) using this improper reasoning is improper.

THE REJECTION DOES NOT PROVIDE A BASIS FOR USING MGD AS SET FORTH IN THE METHOD AS CLAIMED

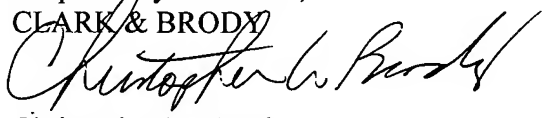
The rejection makes the observation that McAtee discloses MGD as one of many suitable emulsifiers for use as part of the conditioning component. However, the real question is whether it is obvious to use this particular emulsifier in the claimed manner. The questions arise of why pick this emulsifier, add it to petrolatum heated to up to 80 °C, and then dilute it with preheated water. This process of making the claimed absorption base is totally unrelated to McAtee or, for that matter, Narula. The mere fact that McAtee identifies MGD does not lead to practicing the process of claims 6 and 17 and a *prima facie* case of obviousness is not established for this reason.

FINAL REJECTION OF JULY 25, 2008

The Examiner's comments in the final rejection do not change the fact that the rejection is fundamentally flawed. The Examiner has oversimplified the issue of obviousness by characterizing it as the mere use of MGD in Narula. Even if it were obvious to use MGD in the Narula method, the issue is whether the method of claims 6 and 17 are taught. The method steps admitted to be missing in Narula are not found in McAtee since McAtee is completely unrelated to the method of Narula. Again, the invention is not just using MGD in Narula or reordering of the steps of Narula and/or McAtee and the combined prior art does not established a *prima facie* case of obviousness against claims 6 and 17. There is a lack of reasoning to arrive at the inventive methods given the teachings of Narula and McAtee. The teachings of these references are not for the same purpose to support a blanket combination of all of their features. The rejection also fails to properly lay a foundation to allege that the heating step or preheating of water if obvious, or that the processing steps using MGD are obvious.

In light of the above, Appellants respectfully requests that the Panel direct the Examiner to allow this application. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 50-1088.

Respectfully submitted,
CLARK & BRODY



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